

USSN 10/032,370

REMARKS

Pursuant to the Office Action dated July 1, 2009, claims 1-7, 10-22, 33, 34, 45, 48-51 and 53-64 were pending in the application with claims 1-7, 10-22, 33, 34, 45, 48, 49 and 55-64 having been rejected and claims 45, 50, 51, 53 and 54 having been withdrawn from consideration. By this Amendment and Response, claims 1, 5-7, 11, 12, 18, 19, 45, 50, 51, 53-55 and 60-63 have been amended and claims 4 and 22 have been cancelled. All remaining pending claims are believed to be in allowable form and present allowable subject matter.

Amendments to the Claims

Independent claims 1 and 55 have been amended to specify that the inorganic antimicrobial agent is selected from antimicrobial glass and ion-exchange type antimicrobial agents. Applicants have also revised the text of claim 1 to make it more succinct and clear. As revised, in clean form, claim 1 now reads as follows:

A high aspect ratio antimicrobial additive comprising discrete microparticles of an antimicrobial hydrophilic polymer, said microparticles, whose longest dimension is from about 5 microns to about 500 microns, having an aspect ratio is greater than about 2, wherein the antimicrobial hydrophilic polymer comprises i) a water absorbing, water vapor absorbing and wettable hydrophilic polymer whose water absorption at equilibrium is at least 5% by weight and ii) an inorganic antimicrobial metal or metal ion-containing antimicrobial agent in particle form dispersed therein, said inorganic antimicrobial agent selected from antimicrobial water soluble glasses, ion-exchange type antimicrobial agents and combinations of the two.

No new matter is entered as the amendments to claims 1 and 55 merely incorporate elements from former dependent claim 4 as well as the paragraphs [0038] and [0039] of the specification.

Dependent claims 5-7, 18, 19 and 60-63 have been amended to make editorial corrections and modifications to account for the revisions to the claims upon which they depend as well as to ensure proper antecedence for the terms used. In particular, Applicants have corrected the confusion relative to the former use of "ceramic carrier" in claims 6 and 60-63 by now referring to the elements as "ceramic particles." No new matter is entered as these amendments are in the nature of editorial/clarifying amendments and are, in any event, fully supported by the claims as originally presented as well as the specification in general.

Claim 11 has been amended to add reference to polyvinylpyrrolidone and vinylpyrrolidone copolymers and delete the reference to the N-vinyl-2-pyrrolidinone, which is a monomer used in the preparation of the foregoing but is not a polymer. Support for this amendment is found in Paragraphs [0051] and [0052].

Finally, Applicants have also amended withdrawn claims 45, 50, 51, 53 and 54 consistent with the amendments to the examined claims. Specifically, independent claim 45 has been amended

USSN 10/032,370

to require the use of the antimicrobial additive of claim 1. These amendments are being made to make rejoinder more appropriate.

Restriction/Rejoinder

Applicants acknowledge the fact that the examiner has maintained and made Final the restriction requirement. In addressing Applicant's argument against restriction, the examiner states that distinction exists because "the product's release can be altered by comprising the antimicrobial additive in hydrophobic polymer or by incorporating the antimicrobial into a polymer matrix that can alter the release." In addressing Applicants' arguments that no additional search burden is presented, the examiner asserts that a search burden is presented as the inventions require a different field of search and/or the prior art applicable to one invention would not likely be applicable to the other.

Applicants continue to traverse the restriction requirement and respectfully requests rejoinder of the withdrawn claims. Looking at the classes and subclasses already searched (though it is noted several of the Search Notes do not identify any searched classes and subclasses), it would appear that the same art would necessarily be searched for both inventions, particularly in light of the amendment to claim to specify the use of the antimicrobial additive of claim 1. Accordingly, it is believed that rejoinder is appropriate and warranted.

Claims Rejections

Indefiniteness under 35 USC §112

Claims 5-7 and 60-62 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, it is asserted that Applicants' use of the terms "ceramic carrier", "zeolite carrier" and "ceramic particle" is confusing.

By the foregoing amendments, Applicant has amended the rejected claims to consistently use the term "ceramic particle" in reference to the inorganic antimicrobial agent, whether it is a water soluble glass particle or an ion-exchange type particle, especially a zeolite particle. In view of the amendment the rejection is moot and should be withdrawn.

Anticipation in view of Yamaguchi (JP 11-222402)

Claims 1-5, 10-18 and 22 have been rejected under 35 USC 102(b) as being anticipated by Yamaguchi Chiharu et. al. JP 11-222401, machine translation ("Yamaguchi"). It is alleged that Yamaguchi teaches and antimicrobial resin composition in the form of an antimicrobial polymer particle, the latter comprising a hydrophilic polymer having an antimicrobial metallic component chemically bonded to the polymer material. The examiner also identifies a plurality of allegedly common features between the antimicrobial particles of Yamaguchi and the antimicrobial additives of the present application which are said to render the claims anticipated.

Applicants respectfully traverse the rejection and request reconsideration.

USSN 10/032,370

It is well established in Patent Law that a claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 7320 F2d 1452, 1458 (Fed. Cir. 1984); *Alco Standard Corp. v. Tennessee Valley Auth.* 1 USPQ2d 1337, 1341 (Fed. Cir. 1986); *Verdegall Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the...claims." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In following, "there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the filed of the invention." *Scripps Clinic v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). (See also MPEP 2131).

Yamaguchi teaches very specific antimicrobial, cross-linked, hydrophilic polymer particles which can be incorporated into resins, coatings and the like to provide antimicrobial properties. [0036-0041] These hydrophilic polymer parties comprise a plurality of polymerized monomer units including hydrophilic monomer units and monomers containing functional atoms/groups that will chemically bond to an antibacterial metallic component, most notably a sulfur containing moiety. [0031] These chemical bonds are either ionic or coordination bonds, the latter being the result of a chemical bond between a ligand in the hydrophilic polymer and the metallic component. [0006-007] In essence, Yamguchi teaches cross-linked organic polymer particles wherein the organic polymer has a plurality of antimicrobial metal atoms, as ions or otherwise, chemically bonded along the polymer chains. The antimicrobial hydrophlic polymer may be made using monomers that already have the antimicrobial metal component chemically bonded thereto or the hydrophilic polymer can be formed and then subejected to a chemical process whereby the antimicrobial metal components are then bonded to various functional groups along the polymer chain. [0031-0034] Suitable antimicrobial metal atom sources include their metal salts or metallic complexes including, e.g., quarternary ammonium compounds wherein the cation is an antimicrobial metal ion.

On the other hand, while Applicants also employ a hydrophilic polymer particle, Applicant employs inorganic antimicrobial agents in the form of water soluble glass particles and/or ion-exchange type ceramic particles, both of which contain antimicrobial metal ions or metal ion sources. These inorganic antimicrobial particles are physically blended into the hydrophilic polymer matrix. Using the language of Yamaguchi, Applicants' antimicrobial metal active is supported by the water soluble glass or ion-exchange ceramic particle and not the cross-linked hydrophilic organic polymer as is Yamaguchi. (see paragraphs [0007 and 0033-0034])

Although Applicants have addressed Yamaguchi on the basis of the nature of the antibiotic agent and how it is integrated into the hydrophilic polymer, Applicants do not intend to suggest or infer that they accede to the multitude of additional assertions made by the examiner as to the similarities between the Yamaguchi materials and those now claimed. Indeed, the examiner asserts that Yamaguchi teaches the use of an ammonium discoloration inhibiting agent. While, Yamaguchi teaches that its antibiotic metallic component may arise from the use of an antimicrobial metal containing quarternary ammonium compound [0027], the quarternary ammonium compound would not be expected to inhibit discoloration. To the contrary, since silver is the primary cause of discoloration, its use may be a cause of discoloration. Similarly, it

USSN 10/032,370

is alleged that Yamaguchi teaches the use of a ceramic carrier [0040], the examiner's mistaken inference suggesting that Applicant applies an antimicrobial hydrophilic polymer to its ceramic particles. Such is not the case nor is that the teaching of Yamaguchi; rather, in paragraph [0040] Yamaguchi indicates that coatings containing their antibiotic cross-linked hydrophilic polymer particles may be applied to a ceramic substrate. One of ordinary skill in the art would recognize this to refer to the coating of cups, plates, sinks, countertops and the like that are made of ceramic materials. One would not take this to mean micron-sized ceramic particles.

Accordingly, it is clear that none of claims 1-5, 10-18 and 22 are anticipated by Yamaguchi and the rejection should be withdrawn.

Obviousness over Yamaguchi et. al. (JP 11-222402) in view of Hagiwara et. al. (US 4,775,585) and further in view of Makita et. al. (US 20010019727 A1)

Claims 1-7, 10-22, 33, 34, 48, 49 and 55-64 stand rejected under 35 USC §103(a) as being unpatentable over Yamaguchi Chichura et. al. ("Yamaguchi") in view of Hagiwara et. al. ("Hagiwara") and further in view of Makita et. al. ("Makita").

Yamaguchi is cited for the reasons set forth above. However, Yamaguchi is acknowledged as failing to teach the use of zeolites.

Hagiwara is cited as teaching the use of zeolites in polymers. Specifically, Hagiwara is said to teach a polymer article having antibacterial properties resulting from the incorporation of antimicrobial zeolites into the polymer which "show an antibacterial effect at the ion-exchange sites of the zeolite particles." Hagiwara allows that its polymers may be highly hydrophilic (col. 8, lines 7+) and the antimicrobial can be a metal salt of a metal having a bactericidal activity. The examiner further states that the "...particle size of the zeolite can suitably be selected depending upon application fields. When granules or coarse fibers, the particle size may be in the range of a few microns to tens of microns or even above several hundred microns (col. 4, lines 9+)." The examiner asserts that fibers inherently have an aspect ratio of greater than 2 and since the fibers or yarns made therewith can be woven, knitted, etc. they inherently meet the limitations of pending claims 33 and 34.

The examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made "to incorporate the hydrophilic polymer particles containing the metal ingredient because Hagiwara teaches that zeolite defined in the invention has an advantage that the reactivity thereof with a metal having a bactericidal activity...is high, and that its ion-exchange capacity is large...." (First full paragraph of page 8)

Applicants respectfully traverse the rejection and requests reconsideration.

The determination of obviousness requires, in part, a multi-step factual analysis in which one must 1) determine the scope and content of the prior art, 2) ascertain the difference between the claimed invention and the prior art, 3) resolve the level of ordinary skill in the pertinent art, and 4) evaluate evidence in the application indicating obviousness or non-obviousness, including evidence of secondary consideration. *Graham v John Deere Co.*, 333 F2d 529, 142 USPQ 243

USSN 10/032,370

(1964). In making this determination one must establish that a) the prior art included each element claimed with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference, b) that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately, c) there was a reasonable expectation of one of ordinary skill in the art as to the results/success, and d) other findings based on the aforementioned Graham factual inquiries to explain a conclusion of obviousness (MPEP 2143). Failing that, the Examiner cannot have established *prima facie* obvious.

Yamaguchi in view of Hagiwara

Yamaguchi

As discussed above, Yamaguchi teaches very specific antimicrobial, cross-linked, hydrophilic polymer particles which can be incorporated into resins, coatings and the like to provide antimicrobial properties wherein the antimicrobial efficacy is due to antimicrobial metallic components chemically bonded to the hydrophilic polymer chains.

Hagiwara

Hagiwara teaches polymer articles having antibacterial properties as a result of the incorporation therein of antimicrobial metal ion ion-exchanged zeolite particles. These articles may be made according to two different methods. In the first, **antimicrobial** zeolite particles having ion-exchanged antibacterial metal ions are incorporated into the polymer resin. (emphasis added) In the second, zeolite particles are incorporated into the resin and articles formed with the resin are then subjected to a treatment whereby antibacterial metal ions are ion-exchanged with other ions in the available compounded zeolite particles. The Hagiwara articles may be in the form of granules and fibers of small diameter or thickness (Col. 7, lines 55-57) and may be formed of a hydrophilic polymer (Col. 8, lines 14-18). While Applicants acknowledge that the aspect ratio of the fibers are likely greater than 2, the examiner is incorrect in the inference that the so formed granules or fibers may be in the range of a few microns to tens of microns or even several hundred microns. The reference noted (col. 4, lines 9+) is directed to the shape and size of the zeolite particle, not the polymer particle in which the zeolite is incorporated. Furthermore, the examiner's recitation of the definition of a fiber and of Hagiwara's intended application for its fibers leaves no doubt that Hagiwara teaches and employs fibers that are orders of magnitude longer than allowed by Applicants. Certainly, the examiner is not suggesting that Applicants' fibers of no greater than 500 microns in length could have been readily woven or knitted to form antimicrobial yarns or fabrics at the time of the invention.

Discussion

Although the rejection is not exactly clear, as best appreciated, the examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the silver zeolite of Hagiwara as the antimicrobial metallic component of Yamaguchi. Such a

USSN 10/032,370

combination is not only not obvious, it is contrary to and inconsistent with the teaching of Yamaguchi and as well as the very objectives of Yamaguchi.

Yamaguchi teaches against the use of inorganic antimicrobial agents like silver zeolites in polymer resins and coatings owing to a number of adverse properties and characteristics, all as more specifically set forth in Yamaguchi paragraphs [0003-0004]. Indeed, several of these disadvantages including poor dispersion and discoloration [0003], disadvantages also noted by Applicants [0007-0008], are specifically addressed and overcome by the specific antimicrobial hydrophilic polymers of Yamaguchi.

Substituting the antimicrobial zeolites of Hagiwara for the antimicrobial metallic component of Yamaguchi would render Yamaguchi unsuitable for its intended application. Specifically, and as mentioned in the preceding paragraph, such a combination would result in coating where settling of the antimicrobial agent, discoloration and dispersion, among other issues, would be a problem. In essence, the proposed modification negates the very attributes and advantages of Yamaguchi's teachings.

Finally, the proposed combination would completely change the very principal of operation of the Yamaguchi teachings. Specifically, Yamaguchi relies upon available metal atoms of its antimicrobial metallic component to react with and bond to the functional groups or moieties on its hydrophilic polymer chain. For that reason, Yamaguchi employs antimicrobial metal salts and complexes from which the metal ions readily dissociate or which contain the metal atoms in a state that exchange or form complexes via coordination bonds with ligands in the hydrophilic polymers. This differs from Applicant's use of antimicrobial metal or metal ion-containing water soluble glasses and ion-exchange type ceramic particle which are physically blended into the hydrophilic polymer. As noted by Yamaguchi, the chemical bonding of the antimicrobial metal is critical for avoiding settling (the bonded atoms cannot settle) and controlling its release (see Yamaguchi paragraphs [0003 and 0025]).

Thus, one would not look to inorganic antimicrobial water soluble glasses or ion-exchange type antimicrobial agents as suitable antimicrobial metallic components for Yamaguchi's hydrophilic polymer particles. In following, it is well established in Patent Law that acting contrary to the art (MPEP 2141.02 and 2146) and/or modifying the prior art in such as way that makes it unsatisfactory for its intended purpose or changes its principal of operation (MPEP 2143.01) do not give rise to prima facie obviousness. As set forth above, the combination and modification proposed by the examiner fails under each of these circumstances and, hence, prima facie obviousness has not been presented.

Yamaguchi in view of Hagiwara further in view of Makita

The examiner has also acknowledged that the combined teachings of Yamaguchi and Hagiwara do not disclose the use of the sodium nitrate dopant. However, it is asserted that Makita teaches a biocidal material that is excellent in chemical resistance and heat resistance and capable of continuously releasing a microdose of silver ion. It is asserted that the biocide comprises an alkali metallic element (which may be sodium nitrate), hydroxyapatite, and silver ion, copper ion or zinc ion and, optionally, an ammonium compound. The examiner asserts that it would have

Response to 07.01.09 Office Action

- 14 -

USSN 10/032,370

been obvious to one of ordinary skill in the art at the time the invention was made "to incorporate a alkali metallic element such as sodium nitrate in the biocidal since the two inventions have the same endeavor and also because Makita teaches that the biocidal is...capable of continuously releasing a microdose of silver ion...." (Last paragraph of page 8)

Makita

Makita teaches novel biocidal metallic complexes comprising a) one of three of novel biocidal metallic salt compounds prepared by combining a number of different compounds, including at least one alkali metallic compound (such as sodium nitrate), and subjecting the combination to reactive conditions to form the desired biocide, and b) a calcium phosphate. It does not appear that the compounds to be reacted include the antimicrobial metal ions or atoms; rather, it appears that the formed biocides are then subjected to an ion-exchange process whereby the silver ions, copper ions or zinc ions are ion-exchanged into the formed biocide compound. Even though Makita allows for the use of the sodium nitrate, it is used as a reactant and is not combined with the formed biocide as a distinct component. Furthermore, it may well be that the sodium nitrate, if used, is the site of the ion-exchange process whereby the antimicrobial metal ions are incorporated into the biocide compound. Thus, contrary to Applicants' claims where the sodium nitrate is added to aid in the release of the metal ions, in Makita it appears they are associated with the uptake of antimicrobial metal ions.

Discussion

It is well established in Patent Law that a dependent claim based upon an allowable independent claim is also allowable. Accordingly, since the independent claims are allowable for the reasons set forth above, claims 19-21 which deal with the use of the dopant are likewise allowable.

Even if it were to be argued that the independent claims were not allowable, claims 19-21 are not obvious from the combined teachings. As noted above, Makita suggests the use of the sodium nitrate as a reactive ingredient for the preparation of their biocide agent. The antibiotic metal ions do not appear to be added until after the sodium nitrate, if selected, were consumed in the reaction. Applicants' use of the sodium nitrate is in no way suggested or motivated by Makita nor is there anything in Makita that would give one any reason to use the sodium nitrate as used by Applicants or to expect the benefit thereof as attained by Applicants.

Accordingly, prima facie obviousness of claims 19-21 has not been presented and the rejection should be withdrawn and the claims passed on to allowance.

CLAIMS FEES

No additional claims fees are due as the total number of claims has been reduced and there is no change in the number of independent claims.

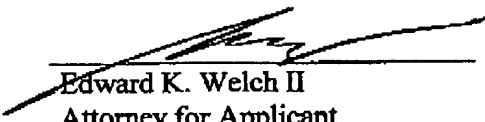
USSN 10/032,370

CONCLUSION

In light of the amendments and the foregoing remarks, Applicants believe the claims as now presented are in allowable form and present patentable subject matter over the art. As discussed at length above, the examiner's assertion that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Yamaguchi by choosing a ceramic carrier such as zeolite taught by Hagiwara and add a sodium nitrate as taught by Makita is unfounded. Prima facie obviousness has not been established and all rejections should be withdrawn and the claims, including the withdrawn claims, passed on to allowance.

It is believed that this response is fully responsive to all of the issues raised in the July 1, 2009 Office Action. If this is in error or if the examiner should have any questions or concerns, the examiner is respectfully requested to contact the undersigned at 781-718-9512.

Respectfully submitted,



Edward K. Welch II
Attorney for Applicant
Registration No. 30,899
IP&L Solutions
4558 Ashton Court
Naples, FL 34112
Tel.: 781-718-9512
e-mail: welched@comcast.net

Response to 07.01.09 Office Action

- 16 -